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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/860,231	07/25/97	THOREL J	WPB-39818

HM12/1013

OLIFF & BERRIDGE
P O BOX 19928
ALEXANDRIA VA 22320

EXAMINER	
WITZ,J	

ART UNIT	PAPER NUMBER
1651	18

DATE MAILED: 10/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/860,231	Thor I et al.
Examiner	**Group Art Unit**
J an C. Witz	1651

[X] Responsive to communication(s) filed on *Jul 22, 1999*

[ ] This action is **FINAL.**

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

[X] Claim(s) *40, 41, 65, 66, and 70-114* is/are pending in the applicat

Of the above, claim(s) *77 and 96-111* is/are withdrawn from consideration

[ ] Claim(s) _____ is/are allowed.

[X] Claim(s) *40, 41, 65, 66, 70-76, 78-95, and 112-114* is/are rejected.

[ ] Claim(s) _____ is/are objected to.

[ ] Claims _____ are subject to restriction or election requirement.

Application Papers

[ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____ .

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[ ] Notice of References Cited, PTO-892

[ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 22, 1999 have been fully considered but they are not persuasive for the reasons set forth below.

Election/Restriction

2. Applicants again traverse the restriction of Group I, claims 19-21, 23-38, and 41 from Group II, claims 22, 39 and 42. The traversal is on the ground(s) that the claims are dependent claims and per MPEP 1850A, unity of invention is considered only in relation to the independent claims, where a dependent claim is meant as a claim that contains all of the features of another claim and is in the same category of claims as the other claim. This is not found persuasive because a further review of that section of the MPEP indicates that

> "If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination. If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation. This method for determining whether unity of invention exists is intended to be applied even before the commencement

> of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art." (emphasis added)

The claims of Group I (containing claims 19-21, 23-38, 40-41 and 43-69), as filed, were determined not to avoid the prior art, and as applied to claims 40-41, 65-66, 70-76, 78-95 and 112-114, have been determined supra to fail to avoid the prior art. Further, claims 96-111, drawn to a composition, now exist as an independent claim followed by dependent and recite a cosmetic composition which may be used as a cell culture medium or in a method of treating wounds, and therefore, at this time fails to avoid the prior art. Therefore, the finding of lack of unity between the original claims is deemed proper and was properly made final in the previous office action, Paper No. 14. Claims 40-41, 65-66 (originally presented) and claims 70-76, 78-95 and 112-114 (newly presented) are considered to still remain in Group I. Claims 96-111 are drawn to the same subject matter as original claim 22 of Group II, and is therefore considered to be withdrawn from consideration as being drawn to a non-elected invention. Applicants are further advised that Rule 144 provides that after a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested

(see § 1.181). [Revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

Claim Rejections - 35 USC § 112

3. Claims 40-41, 65-66, 70-76, 79-95 and 112-114 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim language drawn to "contacting only an area of human skin whose integrity has not been breached by injury" or "contacting only an area of human skin whose integrity has not been breached by a wound" does not find support in the specification as originally filed and is therefore considered new matter. The specification discloses the use of the claimed composition "for topical cosmetic or medicinal use" (Page 1, lines 6-7). The composition is described as being able to "serve as a cosmetic base. Its nutritional provision is considerably advantageous for improvement of the viability, maintenance of the integrity and the balance of the superficial cells of the skin. In particular, it enables the primary intrinsic qualities of the skin to be preserved on a long-lasting basis, its resistance to damage to be increased and, where appropriate, its return to a state of balance to be promoted." (Page 3, lines 28-36). At page 4, lines 6-10, "the use of such a medium on a weakened skin (irritated or dehydrated skins, older skins, etc) enables the skin to return to a satisfactory state, in terms both of trophicity and of hydration of the superficial layers of the epidermis." Further down on page 4, lines 15-27, the specification addresses the uses of the composition such as for "the cleaning and maintenance of grafts in third-degree burns victims" and for "preventing or treating disorders of cicatrization such as bedsores, varicose ulcers, stretch

marks and keloids, and/or a delay of cicatrization." The showings of the specification are drawn to in vitro treatment of cultured keratinocytes and transformed epidermal cells, and in vivo on "the taking of human skin grafts and the prevention of cicatrization disorders." In the latter two cases, it is clear that skin whose integrity has been breachy by injury was treated.

While it is understood that the breadth of applicants' disclosure included cosmetic applications, it is also clear that the selective treatment of normal skin, while any nearby injured skin is avoided, is not disclosed. There are no definitions of the terms "injured" or "breached by a wound" to be found in the specification, and therefore, these terms must be given their broadest reasonable interpretation, and would therefore include the types of skin mentioned above, such as "weakened skin" and "older skin". Therefore, given the disclosure of the specification that specifically teaches to treat that type of skin, the selective treatment of skin not so affected fails to find support in the specification.

4. Claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the complex nutrient medium constitutes an exipient that potentiates an active principal. The specification fails to identify any any active principals which are potentiated by the complex nutrient medium. Therefore, the metes and bounds of the claim are not clear as to what is comprised by the term "active principal" or the term "potentiates".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 40-41, 65-66, 70-76, 78-95 and 112-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of the Lindenbaum patents (5,461,030 or 5,591,709) in view of the Wille, Jr. patents and further in view of Cuca.

The claims are drawn to methods of medicinal or cosmetic treatment where only skin "whose integrity has not been breached by injury" or "by a wound" comprising a composition defined as a complex nutrient medium that permits viable in vitro growth of human epidermal keratinocytes, wherein said composition does not comprise any biological extract of animal or cellular origin or a living, nourishing substrate. It is noted at page 1, lines 23-24, of the

specification that Applicants define "biological extract of animal or cellular origin" as comprising fetal calf serum and at lines 30-31 of the specification, "living, nourishing substrate" as comprising a cellular feeder culture, such as fibroblasts.

Lindenbaum discloses formulations and methods for treating wounds comprising an effective amount of a serum-free cellular nutrient medium in combination with at least one cellular growth stimulating compound. Particularly, Lindenbaum discloses the use of MCDB 153 combined with either human growth hormone, hydrocortisone and/or insulin/transferrin in a delivery polymer. MCDB 153 is a serum-free medium which is known to provide in vitro growth of human epidermal keratinocytes. Lindenbaum particularly states that the composition is "effective for enhancing the growth of cells that surround, have been injured by or are responsible for healing a wound." ('790, col. 5, lines 36-41). Further, Lindenbaum states "the function of the nutrient medium is to provide nutrients to normal, distressed and injured cells and skin which surround or comprise the wound to be treated in order to enhance the growth and repair mechanisms which are responsible for healing of the wound." (emphasis added) ('790, col. 9, lines 49-54).

Lindenbaum teaches that any other serum free nutrient media may be used in the invention. See col. 5, lines 30-50 of 5,461,030. Further, as stated previously, Lindenbaum explicitly teaches the use of the media as a topical composition and teaches the use of a delivery polymer. Wille, Jr. teaches other serum free media useful for the culture of keratinocytes. Cuca

teaches that delivery systems for topical preparations are conventionally formulated as water-in-oil emulsions.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the claimed composition in a manner well known in the art, i.e. two phase topical emulsion, for the purpose of topical administration to human skin "whose integrity has not been breached by injury" or "by a wound" as Lindenbaum teaches that "normal" skin adjacent to the wound benefits from the administration of the nutrient medium and one of ordinary skill in the art would have a reasonable expectation that any "normal" skin or skin "whose integrity has not been breached by injury" or "by a wound" would likewise benefit from a nutrient medium as disclosed by Lindenbaum.

Applicants first attempt to define the term "integrity" as being directed to a cosmetic aspect of the invention and asserts that "one of ordinary skill in the art is well aware that skin is generally not perfectly unblemished. Thus, one of ordinary skill in the art would understand that the phrase 'whose integrity has not been breached . . .' to include skin that is not perfectly unblemished but to exclude skin that has been wounded, in constrast to the wounded skin addressed in Lindenbaum." There is no definition for these terms to be found in the specification, and therefore, must be given their broadest reasonable interpretation. Given the broadest reasonable interpretation, the term "injury" is defined by the dictionary as "damage of or to a person, property, reputation, or thing" and "a wound or other specific damage". The term "damage" is defined as "harm". Therefore, Applicants' assertion that one of ordinary skill in the

art would narrowly define the phrase "whose integrity has not been breached by injury" or "by a wound" as including "blemished" skin is not supported by any evidence of record as there is no definition for the term "blemished" to be found in the specification and clearly "blemished skin" has suffered "harm" or "damage".

Applicants then attempt to differentiate the disclosure of Lindenbaum from their own. They assert that "Lindenbaum is not directed to cosmetics or cosmetic methods at all" and that because Lindenbaum teaches that the composition is effective in the treatment of wounds that "Lindenbaum does not teach or suggest 'contacting only an area of human skin whose integrity has not been breached . . .' with the composition." However, Applicants' assertions and arguments are not persuasive. Lindenbaum clearly teaches the nutrient medium as set forth in the claims. Lindenbaum also discloses that the components of the medium are conventionally used to culture keratinocytes in vitro. Further, Lindenbaum discloses that the nutrient medium has a beneficial effect not only on wounded skin, but also on normal skin that surrounds the wounds. Applicants have provided no evidence that the "normal" skin that surrounds the wound is in any way different from the skin "whose integrity has not been breached by injury" or "by a wound" of their claims. Finally, Applicants' emphasis on the "cosmetic" applications of the claimed method are not persuasive as the scope of cosmetics and pharmaceuticals in the art at the time of the invention were co-extensive as compositions which treat conditions of the skin, to include wrinkles and aging, have both a pharmaceutical and a cosmetic effect. Due to the nature of the

skin, any treatment that promotes the health of the skin is deemed to have a beneficial cosmetic effect.

Finally, arguments drawn to the specific components found in claims 77 and 96-11have not been considered as they are drawn to a non-elected invention.

Therefore, it would have been obvious as the time the invention was made to administer a nutrient medium such as claimed (and disclosed by Lindenbaum) to "normal" skin or skin "whose integrity has not been breached by injury" or "by a wound" with the reasonable expectation of a cosmetic benefit.

7. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on Monday through Thursday from 8:00 to 5:30. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEAN C. WITZ
PRIMARY EXAMINER